

**REMARKS**

Claims 19 and 24 have been amended to clarify the invention. In claim 24, the chemical name of formula 6, depicted in Figure 3, has been amended to contain nomenclature consistent with formula 7, also depicted in Figure 3. Support for these amendments can be found, for example, at page 1, lines 21-23, page 4, line 9, and page 8, lines 7-10 and 15. Claims 20, 21, and 23 have been canceled.

No new matter has been added, and entry of the amendment is respectfully requested.

**Priority**

The position taken by the Office on priority is noted: however, this issue is moot as there are no intervening publications.

**Information Disclosure Statement**

Applicant is submitting concurrently an Information Disclosure Statement.

**Rejection of Claims Under 35 U.S.C. § 112, Second Paragraph**

Previous rejection of claims 19-21 and 23-24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained by the Examiner.

The Examiner rejected all of the pending claims based on the allegation that the terms “macrolactone” and “antibiotic” rendered the claims indefinite.

While the Applicant respectfully disagrees with the Examiner’s reasoning, Applicant has amended the claims without prejudice to focus them on the production of erythromycin derivatives from 6-dEB derivatives. Because an 6-dEB derivative is an unglycosylated counterpart of its corresponding erythromycin, and because the instant specification provides methods for making diverse 6-dEB derivatives and converting them into their glycosylated counterparts by the claimed method, Applicant respectfully submits that the claims, as amended, are not indefinite and so requests withdrawal of this rejection.

Claims 19-21 and 23-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that it is unclear how the adjectives in “heterologously and recombinantly produced macrolactone polyketide” help define the macrolactone compound added to the culture.

While the Applicant respectfully disagrees with the Examiner’s reasoning, Applicant has amended the claims without prejudice to focus them first on the production of erythromycin derivatives from 6-dEB derivatives and second to recite that the 6-dEB derivative used in the process was produced in a recombinant organism other than *S. erythraea*. The specification teaches that 6-dEB derivatives produced in a non-*S. erythraea* host cell, such as *Streptomyces coelicolor*, can be converted into the corresponding erythromycin derivative by adding the 6-dEB derivative to

the fermentation broth of a strain of *S. erythraea*. In view of the amendment to Claim 19 to delete the phrase objected to in favor of “a 6-dEB derivative produced in a recombinant organism other than *Saccharopolyspora erythraea*” and the cancellation of Claims 20, 21, and 23, Applicant respectfully submits that the claims, as amended, are not indefinite and so request withdrawal of this rejection.

**Rejection of Claims Under 35 U.S.C. § 112, First Paragraph**

Previous rejection of claims 20 and 21 under 35 U.S.C. § 112, first paragraph, is maintained by the Examiner.

This rejection is now moot in light of the cancellation by Applicant of claims 20, 21, and 23, and the amendment of claim 24 to depend from claim 19, without prejudice. For the record, Applicant notes that claim 19, as amended, reads on *S. erythraea* strains generally and neither requires nor prevents the use of any mutant strain thereof.

Claims 19-21 and 23-24 stand rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement.

The Examiner states that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Though Applicant respectfully disagrees with the Examiner’s reasoning, Applicant would like to point out that the language added to claim 19 in the Response filed with the U.S. Patent and Trademark Office April 3, 2003, specifically the phrases “heterologous and recombinantly produced

macrolactone polyketide other than 6-deoxyethronolide B (6-dEB)" and "macrolactone polyketide," that caused the new matter rejection, have been deleted from amended claim 19. Thus, the fact that the objectionable language has been removed from claim 19 together with the fact that claim 24 has been amended to be dependent from claim 19 makes this rejection moot.

Furthermore, Applicant has amended claims 19 and 24 without prejudice so as to read on only the production of erythromycin derivatives by fermentation of an *S. erythraea* strain in the presence of 6-dEB derivatives produced in host cells other than *S. erythraea*. Because the instant specification is 1) replete with information concerning polyketides, their glycosylation, and their use as antibiotics, 2) focused specifically on methods to make novel polyketides and glycosylate them, and 3) because the specific Examples describe how the methods can be practiced to make erythromycin derivatives from 6-dEB derivatives, Applicant respectfully submits that the claims, as amended, do not introduce new matter.

Claims 23 and 24 stand rejected under 35 U.S.C. § 112, first paragraph, written description, as maintained above for claim 20.

While the Applicant respectfully disagrees with the Examiner's reasoning set forth in the Office Action, Applicant has canceled claim 20 and amended claim 24 to depend from claim 19, making the rejection moot.

#### **Rejection of Claims Under 35 U.S.C. § 102(e)**

Previous rejection of claims 19 and 20 under 35. U.S.C. § 102(e) as being anticipated by Katz, L., *et al.*, U.S. Patent No. 5,824,513 (hereinafter "the 513 patent") is maintained.

The Examiner states that Applicant's arguments are not deemed persuasive in view of the unclear definition of the word "macrolactone."

The word "macrolactone" has been deleted from claim 19. In addition, Claim 19 as amended, requires that the 6-dEB derivative be produced in a recombinant organism other than *S. erythraea*. As the '513 patent discloses how to make certain erythromycin derivatives in strains of *S. erythraea*, it does not anticipate claim 19 as amended. Thus, the rejection is moot in light of the amendments made to claim 19 and the cancellation of claim 20.

Therefore, Applicant asserts that claim 19 is patentable under 35 U.S.C. § 102(e) over the '513 patent.

**CONCLUSION**

For the foregoing reasons, the Applicants respectfully request allowance of the subject application and claims as amended herein.

If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 300622000212.

Respectfully submitted,

Dated: December 12, 2003

By: Brenda J. Wallach  
Brenda J. Wallach, Ph.D.  
Registration No. 45,193

Morrison & Foerster LLP  
3811 Valley Centre Drive,  
Suite 500  
San Diego, California 92130-2332  
Telephone: (858) 720-7961  
Facsimile: (858) 720-5125